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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/454,740	12/06/99	HILLEBRAND T	2936.166/00

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EXAMINER	
CHAKRABARTI,A	
ART UNIT	**PAPER NUMBER**
1655	7

DATE MAILED: 07/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/454,740	Hillebrand et al.
Examiner	**Group Art Unit**
Arun Chakrabarti	1655

☒ *Responsive to communication(s) filed on* Mar 13, 2000 .

☐ *This action is* **FINAL.**

☐ *Since this application is in condition for allowance except for formal matters,* **prosecution as to the merits is closed** *in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.*

A shortened statutory period for response to this action is set to expire 3 *month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).*

Disposition of Claims

☒ *Claim(s)* 1-11, 26, and 27 *is/are pending in the application.*

Of the above, claim(s) _____ *is/are withdrawn from consideration.*

☐ *Claim(s)* _____ *is/are allowed.*

☒ *Claim(s)* 1-11, 26, and 27 *is/are rejected.*

☐ *Claim(s)* _____ *is/are objected to.*

☐ *Claims* _____ *are subject to restriction or election requirement.*

Application Papers

☒ *See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.*

☐ *The drawing(s) filed on* _____ *is/are objected to by the Examiner.*

☐ *The proposed drawing correction, filed on* _____ *is* ☐*approved* ☐*disapproved.*

☐ *The specification is objected to by the Examiner.*

☐ *The oath or declaration is objected to by the Examiner.*

Priority under 35 U.S.C. § 119

☒ *Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).*

☒ *All* ☐ *Some** ☐ *None of the CERTIFIED copies of the priority documents have been*

☒ *received.*

☐ *received in Application No. (Series Code/Serial Number)* _____ .

☐ *received in this national stage application from the International Bureau (PCT Rule 17.2(a)).*

**Certified copies not received:* _____ .

☐ *Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).*

Attachment(s)

☒ *Notice of References Cited, PTO-892*

☒ *Information Disclosure Statement(s), PTO-1449, Paper No(s).* 5

☐ *Interview Summary, PTO-413*

☒ *Notice of Draftsperson's Patent Drawing Review, PTO-948*

☐ *Notice of Informal Patent Application, PTO-152*

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-11 and 26-27, drawn to formulations for isolating nucleic acids, classified in class 426, subclass 650.

   II. Claims 12-19, drawn to method of isolating nucleic acids, classified in class 536, subclass 25.4.

2. The inventions are distinct, each from the other because of the following reasons: Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the formulations of the buffer system of Group I can be used to isolate or purify nucleic acids of Group II or to purify proteins and lipids.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Bruce Londa (212-968-1300) on July 7, 2000, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11

and 26-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-19 of Group II are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-11 and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected over the recitation of the phrase, "in particular of" and "optional complex starting material". It is not clear whether the words following these phrases are necessary requirements of the claimed invention.

Claim 1 is also rejected over the recitation of the phrase "wash and elution buffers known as such". It is not clear what type of wash and elution buffers are claimed. There are several different kinds of wash and elution buffer solutions known in the art to isolate different chemicals e.g., carbohydrates, lipids and nucleic acids. It is unclear whether all these wash and elution buffers are included in the claimed invention. The metes and bounds of the claim is vague and indefinite.

Claims 2, 4, 9 and 11 are rejected over the use of improper Markush group language. The proper Markush group language, "from the group consisting of" must be used.

Claim 27 is rejected over the recitation of the phrase, "degrading proteins degrading enzymes". It is not clear whether the buffer system contains degrading proteins or contains degrading enzymes or both. The metes and bounds of the claim is vague and indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

9. Claims 1-5, 7 and 9 are rejected under 35 U.S.C. 102 (e) as being anticipated by Anderson et al. (U.S. Patent 5,948,656) (September 7, 1999).

Anderson et al. teach formulations without chaotropic components for isolating nucleic acids with binding to a solid phase (Example I), in particular of DNA, from optional complex starting materials containing:

- a lysis/binding buffer system which contains at least one antichaotropic salt component (Example I, column 15, lines 23-24),

- a solid phase (Example I, column 15, lines 26-27),

- wash and elution buffers (Example I, column 15, lines 27-32).

Anderson et al. teach the formulations wherein the antichaotropic component is sodium chloride (Example I, column 15, lines 23-24).

Anderson et al. teach the formulations wherein the lysis/binding buffer system contain detergents and additive (Example I, column 15, line 24).

Anderson et al. teach the formulations wherein the detergents are Tris-HCl, EDTA, SDS and triton X-100 (Example I, column 15, lines 24-25).

Anderson et al. teach the formulations wherein the lysis/binding buffer system contains an alcohol for binding to the solid phase (Example I, column 15, lines 25-26).

Anderson et al. teach the formulations wherein all carriers serve as a solid phase which were used for isolation by means of chaotropic reagents, glass fiber mats or glass beads (Example I, column 15, line 27).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-7, 9 and 27 are rejected under 35 U.S.C. 103 (a) over Anderson et al. (U.S. Patent 5,948,656) (September 7, 1999) in view of Gonsalves et al. (U.S. Patent 5,907,085) (May 25, 1999).

Anderson et al teach the formulations of claims 1-5, 7 and 9 as described above.

Anderson et al do not teach the lysis/binding buffer system containing enzymes in aqueous solution.

Gonsalves et al teach the lysis/binding buffer system containing enzymes in aqueous solution (Example I, column 35, lines 34-36 and Example 12, column 43, lines 43-49).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute proteinase K of Gonsalves et al. in the lysing buffer of Anderson et al., since Gonsalves et al. states, "Samples prepared with proteinase K-treated crude extract have an advantage over others in that hazardous organic solvents, such as phenol and chloroform, are avoided (Column 43, lines 46-49)". An ordinary practitioner would have been motivated to substitute the proteinase K of Gonsalves et al. in the lysing buffer of Anderson et al., in order to achieve the express advantage of a system, as noted by Gonsalves et al, which has advantage over others in that hazardous organic solvents, such as phenol and chloroform, are avoided.

11. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103 (a) over Anderson et al. (U.S. Patent 5,948,656) (September 7, 1999) in view of Summerton et al. (U.S. Patent 6,060,246) (May 9, 2000).

Anderson et al teach the formulations of claims 1-5 and 7 and 9 as described above

Anderson et al do not teach the formulations wherein the buffer system is a solid formulation stable in storage in reaction vessel ready for use.

Summerton et al teach the formulations wherein the buffer system is a solid formulation stable in storage in reaction vessel ready for use (Column 10, lines 52-57).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute dried buffer of Summerton et al. in the lysing buffer of Anderson et al., since Summerton et al. states, "This pH adjustment can be readily carried out as part of the specimen preparation step, simply by incorporating in the specimen receiving container a suitable buffer, preferably in dry form, effective to adjust the specimen to the proper pH for electrostatic capture of polynucleotides (Column 10, lines 52-57)". An ordinary practitioner would have been motivated to substitute dried buffer of Summerton et al. in the lysing buffer of Anderson et al., in order to achieve the express advantage of a system, as noted by Summerton et al, which provides effective adjustment of the specimen to the proper pH for electrostatic capture of polynucleotides .

12. Claims 1-5, 7, and 9-11are rejected under 35 U.S.C. 103 (a) over Anderson et al. (U.S. Patent 5,948,656) (September 7, 1999) in view of Woodard et al. (U.S. Patent 5,650,506) (July 12, 1997).

Anderson et al teach the formulations of claims 1-5 and 7 and 9 as described above

Anderson et al do not teach the formulations wherein all carriers which have a negatively functionalised surface or functionalised surfaces which may be converted to a negative charge potential serve as solid phase and wherein the surface of the carrier is modified by a hydroxyl group.

Woodard et al teach the formulations wherein all carriers which have a negatively functionalised surface or functionalised surfaces which may be converted to a negative charge

potential serve as solid phase and wherein the surface of the carrier is modified by a hydroxyl group (Abstract and Column 2, lines 40-57 and column 4, lines 44-54).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute the negatively charged surface containing solid phase of Woodard et al. in the lysing buffer of Anderson et al., since Woodard et al. states, "The modified glass fiber membranes of the present invention allows very quick and efficient isolation of DNA from biological samples. They can substantially decrease the time required to process pure DNA from biological samples, compared with currently used techniques, and in some cases generate high quantities of pure DNA (Column 4, lines 44-49)". An ordinary practitioner would have been motivated to substitute the negatively charged surface containing solid phase of Woodard et al. in the lysing buffer of Anderson et al., in order to achieve the express advantage of a system, as noted by Woodard et al, which allows very quick and efficient isolation of DNA from biological samples and in some cases generate high quantities of pure DNA .

13. Claims 1-5, 7, 9 and 26 are rejected under 35 U.S.C. 103 (a) over Anderson et al. (U.S. Patent 5,948,656) (September 7, 1999) in view of Asgari et al. (U.S. Patent 5,858,649) (January 12, 1999).

Anderson et al. teach the formulations of claims 1-5 , 7 and 9 as described above.

Anderson et al do not teach the antichaotropic component ammonium chloride.

Asgari et al teach the antichaotropic component ammonium chloride (Column 9, lines 47-50).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine ammonium chloride as a lysing reagent of Asgari et al. in the lysing buffer of Anderson et al., since Asgari et al. states, "A preliminary step involving lysis of maternal erythrocytes involving, e.g., with ammonium chloride, can conveniently be used to remove a substantial proportion of these red cells (Column 9, lines 47-50)". An ordinary practitioner would have been motivated to substitute the ammonium chloride of Asgari et al. in the lysing buffer of Anderson et al., in order to achieve the express advantage of a system, as noted by Asgari et al, which can conveniently be used to remove a substantial proportion of red cells from erythrocytes to selectively purify white blood cells.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,

Patent Examiner,

July 13, 2000

JEFFREY FREDMAN
PRIMARY EXAMINER